



THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: OSBAKKEN *et al.*
Serial No. 09/942,959
Filed: August 31, 2001

For: AEROSOLIZED ANTI-INFECTIVES,
ANTI-INFLAMMATORIES, AND
DECONGESTANTS FOR THE
TREATMENT OF SINUSITIS

Confirmation No.: 7962
Art Unit: 1616
Examiner: Dewitty, R.

#17
JRP
9/25/03

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
IN ACCORDANCE WITH 37 C.F.R. §§ 1.97-1.98**

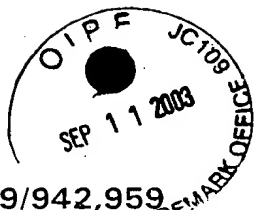
Commissioner for Patents
U.S. Patent and Trademark Office
P.O. Box 2327
Arlington, VA 22202

Dear Sir:

Since this Supplemental Information Disclosure Statement is filed before the receipt of a first Office Action on the merits for the above-captioned application, no filing fee is due. If it is determined that a fee is due, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-1213.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all references known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. The Forms PTO-1449 (9 pages) and the cited references are provided herewith.

The documents listed on the Form PTO-1449 and supplied herewith are in the English language, with the exception of Items BG, BI, BQ, CQ and CS. A certified English-language translation of Item BG is provided (Item CE). English-



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language Derwent abstracts for Items BI and BQ are provided (Items CI and CJ, respectively). English-language abstracts are provided on the last page of Items CQ and CS. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

Applicant also makes known to the Examiner the following U.S. and International applications, which are commonly owned and/or have one or more inventors in common.

<u>U.S.S.N.</u>	<u>Filing Date</u>	<u>Docket No.</u>	<u>Status</u>
09/577,623	05/25/02	1456	Allowed
10/193,081	07/09/02	1456B	Pending
10/231,804	08/28/02	1456C	Pending

<u>Int'l App. no.</u>	<u>Filing Date</u>	<u>Docket No.</u>
PCT/US02/27868	08/31/01	1457PC

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the references, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(h), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.



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Supplemental Information Disclosure Statement

Applicant respectfully requests that the Examiner review the foregoing references and information and that they be made of record in the file history of the above-captioned application.

Respectfully submitted,
HELLER EHRMAN WHITE & McAULIFFE LLP

By:


Dale L. Rieger
Registration No. 43,045

April 14, 2003

Attorney Docket 39187-1457

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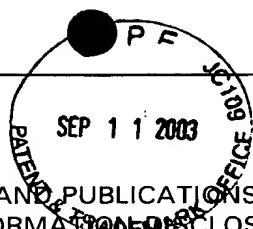
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FORM PTO-1449



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U.S. PATENT DOCUMENTS

EXAMINER INITIAL	*Ref. Code	DOCUMENT NUMBER							DATE	NAME	CLASS	SUB CLASS	FILING DATE
	A	0	0	5	2	3	3	8	05/02/02	Yerxa <i>et al.</i>	514	47	12/03/01
	B	0	0	6	5	2	4	4	05/30/02	Yerxa <i>et al.</i>	514	47	11/09/01
	C	0	1	0	3	1	5	7	08/01/02	Yerxa <i>et al.</i>	514	47	01/03/02
	D	4	3	1	2	8	6	0	01/26/82	Clements	424	199	10/24/80
	E	4	3	5	5	0	2	1	10/19/82	Mahl <i>et al.</i>	424	28	10/29/80
	F	4	4	2	4	2	1	6	01/03/84	Cerami <i>et al.</i>	424	211	07/31/79
	G	4	4	6	8	5	1	3	08/28/84	Kirst <i>et al.</i>	536	16.8	09/07/82
	H	4	4	7	8	8	2	2	10/23/84	Haslam <i>et al.</i>	424	78	05/16/83
	I	4	4	8	6	4	1	8	12/04/84	Watanabe <i>et al.</i>	424	180	06/06/83
	J	4	4	9	3	8	3	1	01/15/85	Takaya <i>et al.</i>	424	180	09/30/83
	K	4	5	5	4	2	6	9	11/19/85	Takaya <i>et al.</i>	514	35	01/24/84
	L	4	5	7	1	3	3	4	02/18/86	Yoshida <i>et al.</i>	424	95	12/04/91
	M	4	5	9	3	0	8	9	06/03/86	Wang <i>et al.</i>	536	13.6	10/31/83
	N	4	6	1	7	2	9	3	10/14/86	Wahlig <i>et al.</i>	514	41	05/23/84
	O	4	6	4	7	6	5	6	03/03/87	Watanabe <i>et al.</i>	536	16.1	08/14/84
	P	4	6	5	6	1	6	0	04/07/87	Takaya <i>et al.</i>	514	41	11/18/85
	Q	4	6	8	4	6	4	3	08/04/87	Buddenbaum <i>et al.</i>	514	204	06/03/85
	R	4	7	4	9	7	0	0	06/07/88	Wenig	514	225.2	04/24/87
	S	4	8	5	5	2	8	7	08/08/89	Watanabe <i>et al.</i>	514	41	09/03/86
	T	4	9	0	6	4	7	6	03/06/90	Radhakrishnan	424	450	12/14/88
	U	5	0	0	4	6	1	1	04/02/91	Keigh	424	450	03/21/88

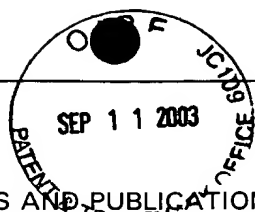
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Title: **AEROSOLIZED ANTI-INFECTIVES, ANTI-INFLAMMATORIES, AND DECONGESTANTS FOR THE TREATMENT OF SINUSITIS**

FORM PTO-1449



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EXAMINER INITIAL	*Ref. Code	DOCUMENT NUMBER							DATE	NAME	CLASS	SUB CLASS	FILING DATE
	V	5	0	0	6	3	4	3	04/09/91	Benson <i>et al.</i>	424	450	12/29/88
	W	5	0	3	9	6	6	6	08/13/91	Novick, Jr.	517	37	10/30/90
	X	5	0	4	9	3	8	8	09/17/91	Knight <i>et al.</i>	424	450	07/21/89
	Y	5	0	4	9	3	8	9	09/17/91	Radhakrishnan	424	450	12/01/89
	Z	5	1	1	0	8	0	6	05/05/92	Clements	514	78	04/07/89
	AA	5	1	1	2	8	0	4	05/12/92	Kowarski	514	3	09/14/89
	AB	5	1	4	1	6	7	4	08/25/92	Keigh	252	305	06/24/91
	AC	5	1	6	7	5	0	6	12/01/92	Kilis <i>et al.</i>	434	262	10/24/91
	AD	5	1	6	9	6	3	7	12/08/92	Kenk <i>et al.</i>	424	450	04/02/91
	AE	5	2	9	9	5	6	6	04/05/94	Davis <i>et al.</i>	128	200	09/18/92
	AF	5	5	0	8	2	6	9	04/16/96	Smith <i>et al.</i>	514	38	10/19/94
	AG	5	5	1	2	2	6	9	04/30/96	Molina y Vedia <i>et al.</i>	424	45	06/09/93
	AH	5	5	2	2	3	8	5	06/04/96	Lloyd <i>et al.</i>	128	203.26	09/27/94
	AI	5	5	2	5	3	2	9	06/11/96	Snyder <i>et al.</i>	424	45	01/03/95
	AJ	5	5	6	7	7	1	6	10/22/96	Della Valle <i>et al.</i>	514	332	11/19/93
	AK	5	5	9	5	9	7	7	01/21/97	Dyrsting <i>et al.</i>	514	39	10/27/93
	AL	5	6	1	4	2	1	6	03/25/97	Janoff	424	450	05/16/95
	AM	5	6	2	4	9	6	2	01/21/97	Dyrsting <i>et al.</i>	514	39	10/27/93
	AN	5	6	5	5	5	2	3	08/12/97	Hodson <i>et al.</i>	128	315	05/22/95
	AO	5	6	8	5	2	9	1	11/11/97	Marsh	128	200.15	11/15/96
	AP	5	8	6	1	2	7	5	01/19/99	Hansen	435	69.1	09/28/95

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EXAMINER INITIAL	*Ref. Code	DOCUMENT NUMBER							DATE	NAME	CLASS	SUB CLASS	FILING DATE
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	AR	5	9	0	0	4	0	6	05/04/99	von Ahlsen <i>et al.</i>	514	35	06/08/94
	AS	5	9	0	0	4	0	7	05/04/99	Yerxa <i>et al.</i>	514	47	02/06/97
	AT	5	9	0	6	1	9	8	05/25/99	Flickinger	128	200.21	07/14/97
	AU	5	9	8	5	2	5	9	11/16/99	Cagle <i>et al.</i>	424	78.04	04/30/97
	AV	6	0	3	7	3	5	8	03/14/00	Gordziel	514	357	03/24/99
	AW	6	0	8	3	9	2	2	07/04/00	Montgomery	514	38	04/02/97
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	AY	6	2	7	7	8	5	5	08/21/01	Yerxa	514	256	04/21/00
	AZ	6	3	3	1	5	2	9	12/18/01	Yerxa <i>et al.</i>	514	47	02/25/00
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	BB	6	4	2	0	3	4	7	07/16/02	Jacobus <i>et al.</i>	514	51	07/17/98
	BC	6	4	2	3	6	9	4	07/23/02	Drutz <i>et al.</i>	514	51	02/21/96
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	BE	6	4	4	8	2	7	6	09/10/02	Yerxa	514	357	05/17/00
	BF	6	4	6	2	1	8	3	10/08/02	Toth <i>et al.</i>	536	17.2	08/26/99

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	*Ref. Code	DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUB CLASS	Translation Yes No	
	BG	1	0	1	3	0	1	48	05/19/98	JP (A)			X	
	BH	0	4	7	0	1	5	4	06/05/96	EP (B1)				

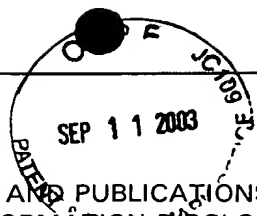
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	BI	0	5	0	7	7	0	7	07/12/95	EP (B1)				+ X
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	BK	0	6	8	2	5	1	4	09/12/01	EP (B1)				
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	BT	9	7	2	9	7	5	6	08/21/97	PCT (A1)				
	BU	9	7	3	5	5	9	1	10/02/97	PCT (A2, A3)				
	BV	9	8	3	4	5	9	3	08/13/98	PCT (A1)				

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

BW	Adelroth <i>et al.</i> , "Airway responsiveness to leukotrienes C ₄ and D ₄ and to methacholine in patients with asthma and normal controls", <i>N Engl J Med</i> , <u>315</u> :480-484 (1986)
BX	Alexandrakis <i>et al.</i> , "Nasolacrimal Duct Obstruction and Orbital Cellulitis Associated With Chronic Intranasal Cocaine Abuse," <i>Arch Ophthalmol</i> , <u>117</u> :1617-1622 (1999)
BY	Baraniuk <i>et al.</i> , "Addition of intranasal glucocorticoids to standard antibiotic therapy for sinusitis", <i>Current Allergy and Asthma Rep</i> , <u>1</u> (3):191-192 (2001)

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BZ	Bell <i>et al.</i> , "A-78773: a selective, potent 5-lipoxygenase inhibitor", <i>J Lipid Mediators</i> , <u>6</u> :259-264 (1993)
CA	Bhattacharyya <i>et al.</i> , "The Microbiology of Recurrent Rhinosinusitis After Endoscopic Sinus Surgery", <i>Arch Otolaryngol Head Neck Surg</i> , <u>125</u> (10):1117-1120 (1999)
CB	Boner <i>et al.</i> , "A combination of cefuroxime and N-acetyl-cysteine for the treatment of maxillary sinusitis in children with respiratory allergy", <i>Int J Clin Pharmacol Ther Toxicol</i> , <u>22</u> (9):511-514 (1984)
CC	Boyce <i>et al.</i> , "MRSA patients: proven methods to treat colonization and infection," <i>Journal of Hospital Infection</i> , <u>48</u> (Supplement A):S9-S14 (2001)
CD	Braun <i>et al.</i> , "Adjunct effect of loratadine in the treatment of acute sinusitis in patients with allergic rhinitis", <i>Allergy</i> , <u>52</u> (6):650 (1997)
CE	Certified English Translation for Japanese Patent Application (Kokai) No. 10-130148 entitled: "Composition for Nebulizers".
CF	Cimochowski <i>et al.</i> , "Intranasal Mupirocin Reduces Sternal Wound Infection After open Heart Surgery in Diabetics and Nondiabetics," <i>Ann Thorac Surg</i> , <u>71</u> :1572-1579 (2001)
CG	Cohen, M.L., "Antimicrobial resistance: prognosis for public health", <i>Trends Microbiol</i> , <u>2</u> :422-425 (1994)
CH	Dahlen <i>et al.</i> , "Leukotrienes are potent constrictors of human bronchi", <i>Nature</i> , <u>288</u> :484-486 (1980)
CI	Derwent# 009206491, W.P.I. Acc No: 1992-333912/199241, for European Patent Application, EP 507707 A, "Control unit for therapeutic nebuliser - has sonic vibration control chamber made separate from over-pressure control chamber and linked to pulsed air source".
CJ	Derwent# 013773627, W.P.I. Acc No.: 2001-257838/200126, for PCT Patent Application, WO 200119344 A1, "Preparing powders for nasal atomization, useful e.g. for administering Vitamin B12, using water insoluble, absorbent excipient to carry active ingredient".

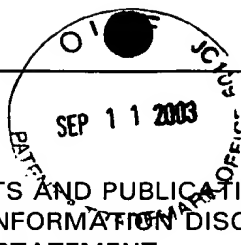
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OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

CK	Desrosiers <i>et al.</i> , "Treatment of chronic rhinosinusitus refractory to other treatments with topical antibiotic therapy delivered by means of a large-particle nebulizer: Results of a controlled trial," <i>ArchOtolaryngol Head Neck Surg</i> , <u>125</u> :265-269 (2001)
CL	Dolor <i>et al.</i> , "Comparison of Cefuroxime With or Without Intranasal Fluticasone for the Treatment of Rhinosinusitis," <i>J Am Med Assoc</i> , <u>286</u> :3097-3105 (2001)
CM	Dunbar, C.A. and A.J. Hickey, "Evaluation of Probability Density Functions To Approximate Particle Size Distributions of Representative Pharmaceutical Aerosols," <i>J Aerosol Sci</i> , <u>31</u> (7):813-831 (2000)
CN	Etkins <i>et al.</i> , "Sinusitis", <i>Nidus Information Services, Inc. Well-Connected Report #62: Sinusitis</i> , www.well-connected.com (2002)
CO	Farr, B.M., "Mupirocin to Prevent <i>S. Aureus</i> Infections," <i>N.E. J Med</i> , <u>346</u> (24):1905-1906 (2002)
CP	Gürses <i>et al.</i> , "Cefuroxime axetil in the treatment of acute sinusitis in childhood", <i>J Antimicrob Chemother</i> , <u>38</u> :547-550 (1996)
CQ	Hiramatsu <i>et al.</i> , "MRSA Infections in an Intensive Care Unit," <i>Masui</i> , <u>49</u> :867-871 (2000)
CR	Hitomi <i>et al.</i> , "Control of a methicillin-resistant <i>Staphylococcus aureus</i> outbreak in a neonatal intensive care unit by unselective use of nasal mupirocin ointment," <i>J Hosp Infec</i> , <u>46</u> :123-129 (2000)
CS	Holmström, M., "Nasal polyposis - of interest to several specialities. Improvements in diagnosis and new treatment methods," <i>Lakartidningen</i> , <u>97</u> (34):3611-3615 (2000)
CT	Jeong <i>et al.</i> , "Intranasal mupirocin for prevention of hospital MRSA infection," <i>ASHP-Mid-year Clin Mtg, Abstract of Meeting Presentation</i> , <u>33</u> (Dec):INTL-21 (1998)
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CV	Knowles, S., "Five-day otitis media therapy. Cisapride monitoring in children. Efficacy of sumatriptan nasal spray. Testosterone for AIDS wasting.," <i>Pharm Prac</i> , (Canada) <u>14</u> :28-30 (1998)
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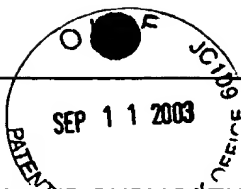
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FORM PTO-1449



LIST OF PATENTS AND PUBLICATIONS FOR
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39187-1457

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OSBAKKEN *et al.*

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1616

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	DC	Meltzer <i>et al.</i> , "Added relief in the treatment of acute recurrent sinusitis with adjunctive mometasone furoate nasal spray," <i>J Allergy Clin Immunol</i> , <u>106</u> :630-637 (2000)
	DD	Nagl <i>et al.</i> , "Activity of N-chlorotaurine against herpes simplex- and adenoviruse", <i>Antiviral Res</i> , <u>38</u> :25-30 (1988)
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	DI	Oszi <i>et al.</i> , "Quantitative determination of polysorbate 20 in nasal pharmaceutical preparations by high-performance liquid chromatography", <u>18</u> :715-720 (1998)
	DJ	Package Insert for: <i>Proventil® (brand of albuterol sulfate)</i> , Schering Corporation, 1986

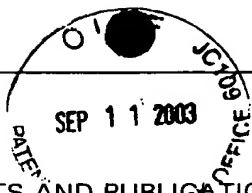
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	DK	Package Insert for: <i>Pulmicort Respules™ (Budesonide inhalation suspension)</i> , AstraZeneca, 2000
	DL	Package Insert for: <i>Pulmicort Turbuhaler 200 mcg (Budesonide inhalation powder)</i> , AstraZeneca, 2001
	DM	Press Release, "Atlantic Technology Ventures, Inc. Licenses World Wide Rights to ATV-02 Antimicrobial Agent", <i>Atlantic Technology Ventures</i> , pgs 1-3, http://biz.yahoo.com/bw/020709/92194_1.html (2002)
	DN	Perkins <i>et al.</i> , "Hemothorax in 2 Horses," <i>J Vet Intern Med</i> , <u>13</u> :375-378 (1999)
	DO	Perl <i>et al.</i> , "Intranasal Mupirocin to Prevent Postoperative <i>Staphylococcus Aureus</i> Infections," <i>N.E. J Med</i> , <u>346</u> (24):1871-1877 (2002)
	DP	Raikhlin-Eisenkraft, B. and Y. Bentur, " <i>Ecbalium elaterium</i> (Squirting Cucumber)- Remedy or Poison," <i>Clin Toxicol</i> , <u>38</u> (3):305-308 (2000)
	DQ	Reicin <i>et al.</i> , "Montelukast, a Leukotriene Receptor Antagonist, in Combination With Loratadine, a Histamine Receptor Antagonist, in Combination With Loratadine, a Histamine Receptor Antagonist, in the Treatment of Chronic Asthma", <i>Arch Intern Med</i> , <u>160</u> :2481-2488 (2000)
	DR	Reiss <i>et al.</i> , "Montelukast, a Once-Daily Leukotriene Receptor Antagonist, in the Treatment of Chronic Asthma", <i>Arch Intern Med</i> , <u>158</u> :1213-1220 (1998)
	DS	Reiss <i>et al.</i> , "Montelukast (MK-0476), A CysLT ₁ Receptor Antagonist, Improves Asthma Outcomes Over a 3-month Treatment Period", <i>Am J Respir Crit Care Med</i> , <u>15</u> (5):A662 (1997)
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	DU	Reiss <i>et al.</i> , "MK-0476, AN LTD ₄ Receptor Antagonist, Exhibits a Dose Related Improvement in the Once Daily Treatment of Patients with Chronic Asthma", <i>Eur Respir J</i> , <u>19</u> (suppl):289S (1995)

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FORM PTQ-1449

SEP 11 2003

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DW	Smith <i>et al.</i> , "The Effect of Inhaled Leukotriene D4 in Humans ¹⁻³ ", <i>Am Rev Respir Dis</i> , <u>131</u> :368-372 (1985)
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DZ	Tsurita <i>et al.</i> , "Early Augmentation of Interleukin (IL)-12 Level in the Airway of Mice Administered Orally with Clarithromycin or Intranasally with IL-12 Results in Alleviation of Influenza Infection," <i>J Pharmacol Exper Therap</i> , <u>298</u> (1):362-368 (2001)
EA	Waltimo <i>et al.</i> , "In Vitro susceptibility of <i>Candida albicans</i> to four disinfectants and their combinations", <i>Int Endod J</i> , <u>32</u> :421-429 (1999)
EB	Wang, J. and G. Bu, "Influence of intranasal medication on the structure of the nasal mucosa", <i>Chinese Med J</i> , <u>115</u> (4):617-619 (2002)
EC	Wang, J. and G. Bu, "Influence of the nasal mucociliary system on intranasal drug administration," <i>Chinese Med J</i> , <u>113</u> (7):647-649 (2000)
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